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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,957	01/11/2001	Robert N. Hanson	ZAA-011.01	9648

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EXAMINER

EPPERSON, JON D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,957

Applicant(s)

HANSON ET AL.

Examiner

Jon D Epperson

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 55-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 and 55-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/6/04 has been entered. Claims 15, 18, 19 and 55-60 were pending. Applicants canceled claims 18 and 19. In addition, Applicants added 61 and 62. Therefore, claims 15 and 55-62 are currently pending. An action on the merit follows.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Withdrawn Objections/Rejections

2. All rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claim Rejections - 35 USC § 112

3. Claims 15 and 55-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The specification as originally filed does not provide support for the invention as now claimed. The specification as originally filed includes only two specific structures that would read on the presently claimed generic (i.e. Figure 9, bottom two compounds). This is deemed to be insufficient support for the newly recited generic that encompasses a wide variety of compounds outside of those compounds presented in Figure 9 (please note that generic formula II does not appear anywhere in the specification and/or the original set of claims). For example, consider just the members of the proposed Markush group for R_1 . The two compounds of Figure 9 contain a $-CO_2H$ group at this position only. So, there is only support for the proposed $R_1 = -CO_2R_4$ where $R_4 = H$ i.e.; Applicants only provide support for $R_1 = -CO_2H$. However, R_1 also recites " $-CO_2N(R_4)_2$ " and R_4 also recites alkyl. The $-CO_2(H)$ is not sufficient support for $-CO_2N(alkyl)_2$ or $-CO_2(alkyl)$. For example, Hydrogen and alkyl groups are NOT bioisosteres (i.e., interchangeable) because they have different size, shape, electronic distribution, lipid solubility, water solubility, pK_a , chemical reactivity, and hydrogen bonding (e.g., see Silverman et al., pages 19-23). For example, an alkyl group attached to a carboxylic acid (i.e., the "R" portion of the $-CO_2R$ ester group) cannot undergo hydrogen bonding like the hydrogen atom that is attached to a carboxylic acid can (i.e., the "H" portion of the $-CO_2H$ acid group). In addition, the alkyl groups are larger than the hydrogen and more lipophilic and have much higher pK_a values. Thus, Applicants' example of a hydrogen atom at the R_4 position does not provide support for an alkyl group at this same position because these groups would have significantly different physiochemical properties (as mentioned above) and thus do not have similar structural features and/or reactivity. Moreover, the $-F$ atoms in the para positions of the GBR 12935 phenyl rings do not supply support for H, F, Cl, Br or I in those positions. In addition, the $-H$ in

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the ortho and meta positions of the GBR 12935 phenyl rings do not supply support for H, F, Cl, Br or I in those positions.

Response

4. Applicant's arguments directed to the above New Matter rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from its original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue, "Support for the new claims can be found throughout the specification, especially in Figures 9-12" (e.g., see 10/6/04 Response, page 1, paragraph 1).

This is not found persuasive for the following reasons:

The Examiner contends that this argument does not address the new matter issue with regard to claims 15 and 55-60 as it pertains only to the "new" claims. Furthermore, the Examiner notes that Applicants have not addressed any of the issues set forth in the rejection above (or mention in the 9/7/04 Advisory action).

Accordingly, the New Matter rejection cited above is hereby maintained.

New Rejections

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 61-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Dutta et al. (Dutta, A. K.; Coffey, L. L.; Reith, M. E. A. "Potent and Selective Ligands for the Dopamine Transporter (DAT): Structure-Activity Relationship Studies of Novel 4-[2-(Diphenylmethoxy)ethyl]-1-(3-phenylpropyl)piperidine Analogues" J. Med. Chem. 1998, 41, 699-705).

For *claims 61-62*, Dutta et al. (see entire document) disclose compound GBR 12909 and compositions using said compound to target DAT (e.g., see Dutta et al., Introduction; see especially Chart 1, compound GBR 12909; see also Experimental section and cited references), which anticipates claims 61-62.

Conclusion

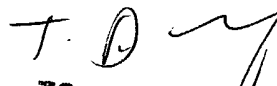
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
December 23, 2004


T.D. WESSENDORF
PRIMARY EXAMINER